Post- Approval Inspection Reporting, Team Biologics

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Objectives:

- Brief reminder: purpose of CBER's cGMP inspection program
- Team Biologics: How cGMP inspection program activities for CBER differ from those for other FDA Centers
- Reporting
- Questions

Purpose of CBER's Inspection Program

- To protect and enhance the public health through regulation of biological and related products, including blood and diagnostics, vaccines, cellular and gene therapies, biological therapeutics and related drugs and devices, according to statutory authorities
- The regulation of these products is founded on science and law to ensure their purity, potency, safety, efficacy and availability

CBER's program vs inspections for other Centers

- FD& C Act : biennial good manufacturing practice (GMP) inspections for drugs and devices for human use, and for animal drugs (*post-approval inspections)*
  - 361 of PHS Act for tissues
- All GMP biennial inspections led by ORA
- Biennials only met for CBER's products

Team Bio Core Team Inspections

- GMP post-approval:
  - assess compliance w/GMP regulations and license commitments
  - firm-specific assignments
  - led by ORA GMP expert w/ CBER scientist participation by consult or in person
  - issuance of FDA-483 (...now what do I do?)
  - Establishment Inspection Report (EIR)

Team Biologics: Inspections and Reporting

- Discuss with investigators during inspection
- Receive a FDA-483? Response = optional
  - Copy to local district office and to FDA-483 masthead address
  - Who may obtain my 483 or response?
  - Posting on FDA website if 3 or more requests

Team Bio reporting and evaluation

- Report evaluation: CBER/OCBQ and ORA/OE joint review of significant violations (not sequential)
  - Firm response to FDA-483
  - Includes product office input; may impact other Centers' products
- Transfer of inspection lead:
  - Fractionators - Fall 1997
  - IVDs - April 1998
  - Biotech & Allergenics - October 1998
  - Vaccines - October 1999